ETHICS OF RESEARCH PUBLISHING

Confidentiality and the ethics of medical ethics

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In this paper we consider the use of cases in medical ethics research and teaching. To date, there has been little discussion about the consent or confidentiality requirements that ought to govern the use of cases in these areas. This is in marked contrast to the requirements for consent to publish cases in clinical journals, or to use personal information in research. There are a number of reasons why it might be difficult to obtain consent to use cases in ethics. Many cases concern people who are incompetent, and thus unable to give consent. Often the material is of a sensitive nature, it is not clear who should give consent, or the ethicist has no access to those involved. We argue that the use of cases in ethics research and teaching can be justified by appeal to the public interest argument, and suggest a number of areas for discussion and clarification.

Ethicists tend to rely heavily on case studies both in research publications and teaching. Such cases are most valuable where they draw attention to new or emerging issues in medical ethics, as these can challenge the limits of current ethical practice, preparing undergraduates and practitioners alike for decisions they may have to make in the future. Examples include the discussions initiated by elective reduction of twin pregnancies,[1] preimplantation selection of genetically compatible fetuses to act as donors for existing siblings,[2] and the unexpected death of a research participant.[3] The implications and limits of current ethical theory can be explored through the analysis and discussion of such cases, making important contributions for health professionals and ethicists alike. For teaching, case studies offer vivid and dramatic examples of what might otherwise seem like dry theoretical problems. Despite some reservations, the use of cases for teaching medical ethics is widespread.[4 5] Cases that illustrate good practice can be the backbone of thoughtful teaching, but sometimes there is a temptation to favour the dramatic in order to capture the interest of students.[6]

Some of the landmark case studies used in ethics come from the public arena, often after a court case, such as the recent case of Ms B requesting discontinuation of her treatment with a ventilator.[7] At least some of the source material for these cases comes, however, from the information disclosed to ethicists by clinicians, either seeking advice about real patients currently under their care, or presented out of interest. It seems natural for an ethicist to suggest that novel cases are "written up" with the clinician. This material also works its way into lectures and seminars, for it is almost impossible not to use new and interesting material that has come to the ethicist's attention.

Given that the use of case studies is both integral to the work of medical ethicists and widespread, it is worth asking whether the use of cases in medical ethics research and teaching breaches confidentiality, whether these breaches can be justified, and what conventions might govern their use in research publication and teaching.

THE CURRENT SITUATION

We checked the information for authors on the websites of several medical ethics journals and found no instructions regarding consent from patients as a prerequisite to the publication of case studies. This is in contrast to many mainstream medical journals which now require the written consent of patients before accepting case studies for publication. (See table 1)

We reviewed all issues of the *JME* published between 1982 and February 2002, focusing on two particular series of articles: "At the coal face" and "Case conference", both of which tend to discuss case material. We excluded those articles that did not discuss personal information, and where an article used more than one case, each case was documented separately. We wanted to know, rough and readily, how often consent was obtained and/or documented, whether the case was anonymised, and what kind of barriers to consent were present, such as the patient being incompetent or deceased, or the case involving more than one person. The results are shown in table 2.

ANONYMISING ETHICS CASES

The prevailing, albeit largely unspoken convention is for ethicists automatically to anonymise case material in recognition of the importance of medical confidentiality, although this was documented in only four out of 31 cases reviewed above (see table 2). But there are problems with this practice. Personal details are often central to the ethical issues of the case. The patient's age, ethnicity, family background, gender, and occupation may all be as important as their specific medical details. For example, our thoughts about paternalism and autonomy in a specific case may well be influenced by information about the gender, ethnicity, and occupations of those involved. The importance of these contextual details means they cannot easily be removed from the case or changed in any substantial way in order to protect the identity of the patient. If they were, the case might simply no longer be noteworthy. In some cases, it may be possible to change details, but it is not clear how many details need to be changed to preserve anonymity. The current view of some medical editors is that it is impossible to guarantee anonymity simply by making some changes to the details of the case, and there have been instances of patients recognising themselves and complaining.[10]

Table 1 Major journals and their requirements for consent and/or anonymisation

Journal title	Instructions to authors re consent*	Instructions to authors re anonymisation*
Ethics Journals		
Bioethics	No instructions	No instructions
Hastings Center Report	No instructions	No instructions
Journal of Clinical Ethics	No instructions	No instructions
Journal of Medical Ethics	No instructions	No instructions
Kennedy Institute of Ethics Journal	No instructions	No instructions
General Medical Journals		
Archives of Internal Medicine	No instructions for case studies. Written consent required for clinical images.	Anonymise by assigning numbers or fictional names to patients.
BMJ	Written consent required if "any chance patient may be identified". Patient to view manuscript prior to publication.	Withhold names, patient details not to be changed to try to disguise them. Patients to understand that complete anonymity cannot be guaranteed.
JAMA	Written consent required from patients who can be identified in written descriptions, photographs, or pedigrees. Patient to view manuscript prior to publication.	No instructions
The Lancet	Written consent required for all case studies. Patient to view manuscript prior to publication.	Withhold names. Patients to understand that complete anonymity cannot be guaranteed.
New England Journal of Medicine	No instructions but links to website of International Committee of Medical Journal Editors displaying the Uniform Requirements for Manuscripts Submitted to Biomedical journals.	See box 1

*Information obtained from the "Instructions for authors" section on the website of each journal.[8]

It seems likely that, despite our best intentions, it is possible that patients could be identified, either by themselves or by someone who knows them, through the cases that are used for teaching and publication.

OBSTACLES TO GAINING CONSENT

One obvious solution to this issue is for ethicists to gain the consent of patients before publishing any information about patients or using this information in teaching. But there are problems with this suggestion. The first and most urgent is that at least some of the patients featured in cases studies are not competent to give consent; eleven out of 31 in our series. In our experience this is a problem that is already hindering the publication of valuable case studies in disability studies and psychiatry. It is hardly in the best interests of the patients concerned for this information to be published and in the case of incompetent adults, there is no one who can give consent on their behalf. Of course, in the case of children, parents can consent but to ask them to do so contravenes the ethical convention that consent should not be sought for non-urgent, irreversible interventions that could wait until the child was able to decide for him/herself at a later date. Since the publication of a case study is not in the medical best interests of the child concerned, and since once in the public domain the information cannot be recalled, it would seem most ethical to wait until the child reaches majority so as to permit her to consent for herself. By this time, however, the case study will be out of date. This is obviously a problem for paediatric medicine case studies and one that has not yet been addressed.

Competent patients may not wish to consent to publication of their cases, as by their very nature, cases of ethical interest tend to be about sensitive issues, about problems in the doctor/patient relationship, or about accidents or mishaps. It is hard to imagine, for example, how an ethicist could gain permission from a couple to write about misattributed paternity discovered accidentally through genetic testing when there is no consensus as to whether the couple themselves should be told of the finding.[11] In addition, sometimes the issues raised by a case are not to do with that patient as such, but raise questions about the organisation of care, or relations between health care professionals. In this situation, the events surrounding the patient serve as a trigger to the wider issue, but the case is as much about other people as it is about the patient, making it difficult to identify who should be the person to give consent. Likewise, some cases involve many

Box 1 Protection of patients' rights to privacy

Patients have a right to privacy that should not be infringed without informed consent. Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that the patient be shown the manuscript to be published.

Identifying details should be omitted if they are not essential, but patient data should never be altered or falsified in an attempt to attain anonymity. Complete anonymity is difficult to achieve, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of patients is inadequate protection of anonymity.

The requirement for informed consent should be included in the journal's instructions for authors. When informed consent has been obtained it should be indicated in the published article.[9]

Table 2 Consent in 31 cases published in the *JME* 1982–2002

Consent for publication	
Documented that consent obtained	0
Documented that consent not obtained	0
No mention of consent	31
Patient apparently competent to give consent at some stage	18
Declaration that case anonymised (or similar)	4
Barriers to consent: competence	
Patient not competent to give consent	11
Unable to clarify or competence disputed	2
Barriers to consent: deceased patient	
Incompetent patient died as part of case	4
Competent patient died as part of case	8
Barriers to consent: more than one person involved in case	
Case involved more than one person	12

different players and may disclose personal information about the patient's family, partner, or friends which they would recognise and which they might not be happy to have in the public domain.

Another problem is that the ethicist does not necessarily have access to the patients concerned in order to gain their consent. Indeed, it is considered desirable for clinicians to withhold the identity of patients when discussing them with ethicists. For published case studies, the clinician could be asked to approach the patient for permission, but in addition to the problems already highlighted the patient may be dead, or the case may have occurred in the distant past or in another country.

The way that this request was worded would have significant implications. The forms currently used by medical journals such as the *BMJ* do not mention research, but are simply requests for consent to publication. If, however, the use of case studies is recognised as ethics *research*, ethicists would need to be prepared to submit their proposals for research using cases to ethics committees, and to develop appropriate patient information materials and consent to research forms.

POTENTIAL HARMS

If a patient is recognised or recognises him or herself in a case study, what are the harms that may occur? The main harm is the experience of violation of privacy that comes from having information that was given in confidence disclosed in the public arena. However, it is not clear how this works in practice if there has been some anonymisation so that an individual may recognise that this case is *like* their case, without being certain this is *indeed* their case. If the case is of a type that may be common to several unconnected people, and there is nothing to link it with a specific individual, then there may be no breach of confidentiality in the sense of having the *personal* details of the patient entering the public domain without consent. People may think they recognise themselves or someone they know, but it is not clear that the privacy objection holds if no one realises, or can be certain, that the information is about a specific person.

There are, however, difficulties with this reasoning. The first is that the biggest indicator that a case is about a particular individual is the geographical location of the author and their name. Anonymous authorship is unlikely to be attractive to many authors, as they belong to a system that largely measures the value of academics (and their institutions) by publication output. Second, what makes at least some of the cases so useful is that they are novel, and therefore the information might only match one individual.

Perhaps more importantly, there are dangers if we think that the only harm from a breach of confidentiality is *experience* of violation of the privacy of specific individuals, as on this line of reasoning, no harm would be done if the person never found out, either through chance or because they are not capable of knowing. This would offer no protection to the incompetent, the deceased, and others. We need to find a balance between protecting privacy to the extent that no personal data (anonymous or otherwise) enters the public arena without consent, and assessing violation of privacy only in terms of being able to recognise personal data.

PUBLIC INTEREST ARGUMENT

Given the problems with guaranteeing anonymity, and the difficulties of obtaining consent, is it possible to justify the publication of patient information without consent, or even against the expressed wishes of the patient, with reference to the public interest argument? There are at least two possible ways in which a public interest argument could be mounted in this context. The first is that it is in the public interest to know what kind of ethical dilemmas are occurring in health care and what kind of decisions are being made by doctors. Given the poor history of the media in fostering balanced debate about ethical issues,[12] it may be fair to claim that analysis and discussion by ethicists and others in academic journals is the best way for this to proceed, or at least that this makes an important contribution to public debate. History suggests the public interest is not served when ethical matters are discussed by unidentified individuals behind closed doors, as, for example, happened with early decisions about transplant recipients. There has been intense public interest in ethical issues in the UK; it was the public's reaction to the development of in vitro fertilisation (IVF) infertility treatment that sparked off sufficient concern to result in the Warnock committee's investigation and the subsequent *Human Fertilisation and Embryo Act 1990*. This suggests there is a significant public interest in being made aware of and informed about ethical issues in health care.

This line of reasoning is similar to that used to justify the use of patient data in epidemiological research, when the benefits to society of the research are considered to outweigh the harms of using anonymised data without consent. This is a very grey area, however, as there is no consensus as to what is in the public interest. Approval from an ethics committee can provide some reassurance, but this does not protect researchers from either professional or legal sanctions. Ultimately it is the courts that have the power to determine what is in the public interest.

The second justification for using case studies in research and teaching is that it is in the public interest to have medical practitioners who have received good training in ethical practice, and that this is best achieved by the use of case studies. Certainly the current consensus in medical ethics education is that case studies are invaluable, and the use of cases is not confined to teaching ethics.[13] There is an expectation that medical students are legitimate recipients of health information and that they are bound by the standards of medical confidentiality. There does not seem to be any important difference between using cases for teaching ethics and using them for teaching communication skills or general practice or any other medical subject.

In summary, it seems that the use of cases in medical education is largely unproblematic and that any regulation of use should apply equally to the use of cases in all branches of clinical teaching. The disparity occurs in research, where cases are the raw data for ethics research, but at present are not subject to the same consent requirements as other forms of research data collection, analysis, and publication.

WHAT SHOULD WE DO?

If we accept that it is difficult to anonymise ethics cases, and if we accept that this is a breach of confidentiality, and if we further accept that it is not possible to obtain patient consent in many cases, then we are faced with some stark choices. We either have to abandon all unauthorised use of cases in teaching and research, or we have to accept that it is in the public interest for these activities to proceed, but that it is time to clarify some issues and raise the standards. These are some of the specific issues that we believe should be considered.

What kind of standards should obtain for publication of case studies?

The ideal standard would be for patients to give written consent for the use of their information. This would allow full discussion of all relevant material in a transparent manner. We recognise that this is not possible in many cases, but where consent has been given, this should be clearly stated.

If it is not possible to obtain consent (and who should judge this is another question), we can perhaps look to some of the discussions about the use of information without consent in other contexts.[14–19] Even strong proponents of informed consent such as Doyal set out conditions in which it might be

acceptable to use information without consent, and one of these conditions is that for practical reasons, consent is hard to obtain.[14] The issue is then whether the practical obstacles we have outlined above are considered sufficient to invoke this justification. Certainly, ethics research is similar to epidemiological research in that there is no question of the research affecting the patient's present or future care, and no intention to contact the patient for reasons related to the research, thereby meeting another of Doyal's requirements.

It may, however, be more fruitful to consider a different line of reasoning, as suggested by Warnock; that is whether or not the use of cases exploits the patients in question.[20] Warnock is not writing with ethics research in mind, but she argues that exploitation is unlikely if there are no harms to the patient involved, where the concept of harm is understood in a fairly robust way. Exploitation is hard to define or measure, but certainly cases may be written up in either a more or a less respectful way. If cases are used to try to further our understanding of ethical issues and, through this, to support high standards of ethical practice, then this does not seem to be exploitative. If cases are used for their shock horror value to increase the standing of the ethicist in the eyes of medical students, this may well be exploitative. If cases are used to engage in intellectually stimulating but essentially solipsistic arguments, then perhaps it is better to use thought experiments rather than cases about real people.

With regard to the public interest argument, many of our landmark ethics cases do come before the courts and so enter the public arena. There are, however, cases that do not come to the courts that are of great public interest, and we feel that it is important to be able to write about and discuss the issues raised by these cases. Again, it is not easy to define exactly what constitutes a landmark case, but the use of experienced referees and editors will help to identify novel issues and weed out repetition.

Where it is possible to anonymise cases, this of course should be done. The name and, where possible, the age of the patient involved should always be changed. Beyond this, it is difficult to be prescriptive. Perhaps we need to adopt a stylised presentation format in which readers and students are always invited to "Imagine a case . . .". This might require the use of "fictionalising editors" to edit cases to the required format. We need to distinguish carefully between the information that is necessary to understanding the case, and the information that adds colour but is not strictly necessary. It is important to recognise that any account of a case may make people aware of more of the facts than they were previously, for example, if a person recognises that a case is about her neighbour, the published account may give her more information than she originally had.

Sometimes it is not clear whether anonymisation has occurred (table 2). We think that for journal publication, anonymisation should be documented, but should this include the nature of the anonymisation? This might have advantages, but could also be potentially more identifying if the patient involved realises that s/he differs from the case only in respect of those features that have been changed.

What kind of standards should obtain for the use of case studies in teaching?

For teaching, the same kind of standards should apply as for teaching in other branches of medicine. Students need to understand that ethics cases are subject to exactly the same confidentiality requirements as other clinical material. Ethicists should set high standards in their use of cases, using only as much material as is necessary and avoiding any kind of sensationalism.

Should ethics research fall under the same regulatory framework as other research using patient data?

This is a tricky area; the nature of ethics research does not seem to be always well understood outside ethics circles. Research based on case studies occupies an uneasy ground between empirical and theoretical research; on the one hand it is obviously different from a qualitative study or an intervention trial, but on the other hand, it does use real patient data. If we accept that there are harms to patients from non-intervention research such that these require ethical scrutiny by a research ethics committee,[21] perhaps we should have the same standards for ethics research. This does seem, however, to be overkill and it is unlikely that ethics committees would welcome the further workload. Also it is not just medical ethics that is struggling with current standards for confidentiality in research. We have already alluded to the problems of presenting case based material about incompetent adults in disability studies and psychiatry; publication of family pedigrees in genetics research also raises some of these issues.[22] Emerging very strict data protection legislation is causing problems for researchers who work with medical records, or with epidemiological data and tissue banks where there is no expectation that identifiable patient information will be reported. Perhaps debate about ethics research should form part of the larger debate about developing workable standards for confidentiality in research.

Who is professionally responsible for breaches of confidentiality?

Doctors and other health care workers have an almost absolute obligation to protect patient confidentiality.[23 24] Ethicists on the other hand, do not have any obvious statutory or professional obligations to patients. The nature of the relationship between an ethicist and the patient about whom they are consulted is undefined, and it is likely that in countries without a recognised/formal system of clinical ethicists, most patients are unaware that their doctor has consulted an ethicist about them. Despite this lack of formal clarity, most ethicists would consider themselves bound by accepted standards of confidentiality, at least in relation to the health care of specific patients. In the UK the General Medical Council (GMC) states that anyone receiving personal information in order to provide care is bound by a legal duty of confidence, irrespective of their contractual or professional obligations, and it seems reasonable to consider that this should apply to ethicists in their capacity of advising about specific patients.[23] The use of this data for any other purposes, such as teaching or research, will breach confidentiality unless the patient has given consent, or the data is anonymised.[25]

Ethicists who are not also practising health care professionals are unlikely to have professional indemnity. Patients may well seek redress from any treating health care practitioner who breaches confidentiality by disclosing information to the ethicist, unless this disclosure was authorised. Patients may also seek redress from journals publishing identifiable material. At the very least, ethicists should discuss the matter with their source clinicians before using a case for teaching or research, firstly to ensure that the pertinent details are correct, and secondly to secure their assistance in anonymising. In terms of the accuracy of the facts, there is also the problem of libel if a patient/worker is presented in a light that s/he considers unfavourable and which is based on a reported *impression* of the facts.

CONCLUSION

We believe that ethics research and ethics teaching which use cases are valuable activities. To date there has been very little discussion about the ways in which these activities may breach patient confidentiality. As a professional group, we need to debate the issues raised in this paper, and to develop practical standards for publication. The irony will not be lost on our colleagues in medical publishing if it is cases in ethics journals that are found to breach confidentiality. Ethics research does raise its own issues with regard to the

difficulties of anonymisation, but shares common ground with other types of research in terms of struggling to comply with the current standards. We all need to work towards standards that protect patients while allowing teaching and research that are very much in the public interest.

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